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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,609	10/09/2001	Shlomo Gabbay	SHEP5010US	8158
26294	7590	10/22/2003		
TAROLLI, SUNDHEIM, COVELL & TUMMINO L.L.P. 526 SUPERIOR AVENUE, SUITE 1111 CLEVEVLAND, OH 44114				
			EXAMINER PELLEGRINO, BRIAN E	
			ART UNIT 3738	PAPER NUMBER 10

DATE MAILED: 10/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/973,609

Applicant(s)

GABBAY, SHLOMO

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-28 and 48-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-28 and 48-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,7. 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election of Species VI: prosthesis and Species C: deployment device in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Objections

Claims 17,27 are objected to because of the following informalities: in line 2 of the claims the recitation of a "biocompatible" appears to be incomplete. Did applicant leave out the word **material**? Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 53-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 53 recites the limitation "the cylindrical member" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim. There are two recitations of a "cylindrical" element in claim 18 from which claim 53 depends. It is unclear which one exactly is being referred to.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2,17-21,27,28,48,49,51,53,54,56,58-60 are rejected under 35

U.S.C. 102(b) as being anticipated by Bessler et al. (5855601). Fig. 4 shows a heart valve prosthesis with a valve **35** mounted within a support having a plurality of support features **33** and an outer sheath **37**. Bessler et al. also disclose the heart valve prosthesis is implanted using an enclosure or catheter that receives the prosthesis and is discharged by what can be construed as a plunger, col. 4, lines 53-66. With respect to claim 21, the support structure can be made of shape memory alloy, col. 6, lines 3-5. Regarding claims 28 and 60, Bessler discloses the valve can be an animal heart valve, col. 6, lines 19-21.

With respect to claims 49,54 the cylindrical member can have a diameter about 15mm since the stent can have this diameter, col. 6, lines 14,15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-16,22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bessler et al. '601 in view of Shokoohi et al. (6077296). Bessler et al. is explained supra. However, Bessler does not disclose a plurality of supports with the biasing element being in the form of a spring and a connecting element in the form of a cord to limit the outward radial expansion of the prosthesis. Shokoohi et al. teaches (Fig. 2) an expandable prosthesis with a plurality of support features **54** joined by connecting element **56**. It can also be seen at the proximal and distal ends **55,59** that the projections extend radially outward and are triangular. Shokoohi also teaches that suture can be used to limit the outward expansion, col. 7, lines 32-39. Shokoohi also shows (Fig. 11) that the support features can have springs **60** at the ends for receiving the suture so sections attached will not separate. It would have been obvious to one of ordinary skill in the art to use additional supports and flared ends as taught by Shokoohi et al. with the prosthesis system of Bessler et al. such that a larger device can be used to accommodate a larger individual or area of treatment and also provide better anchoring ability within the vessel. It would have been obvious to one of ordinary skill in the art to modify the bends (34) of Bessler and incorporate the springs of Shokoohi such that it provides better attachment structure that will not separate.

Claims 50,55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bessler et al. '601 in view of Snyders (6540782). Bessler et al. is explained supra. However, Bessler does not disclose a handle portion attached to the body placed in the cylindrical member. Snyders teaches (Fig. 4) a handle **84** attached to the body of the pushing device. It would have been obvious to one of ordinary skill in the art to use a

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handle as taught by Snyders with the pushing device of Bessler such that accurate control of the delivery device can be accomplished by the surgeon.

Claims 52,57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bessler et al. '601 in view of Torossian (5851210). Bessler et al. is explained supra. However, Bessler does not disclose indicia along the exterior of the cylindrical member. Torossian teaches (Fig. 2) indicia **54** is placed on the cylindrical member or catheter. Torossian also teaches the indicia is used to facilitate implantation of the device, col. 6, lines 26-28. It would have been obvious to one of ordinary skill in the art to use indicia on the delivery device as taught by Torossian with the system of Bessler such that accurate placement can be made by the surgeon.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 9am to 6:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

TC 3700, AU 3738
Brian Pellegrino

Brian Pellegrino